

REMARKS

Claims 1-3 and 9-16 are currently pending in this application. Applicants have withdrawn claims 3-8 and 17-25 from consideration without prejudice in response to a restriction requirement and added new claim 26. Reconsideration is respectfully requested in light of the above amendments and the following remarks.

The Examiner rejected claims 1, 2, and 9-16 under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. The Examiner alleges that the language "from only a portion of a first ... from only a portion of a second" in claims 1 and 16 is not disclosed in the original disclosure and thus fails to comply with the written description requirement. Applicants disagree.

A lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993), (see MPEP §2173.05(i)). Rather, under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). (see MPEP §2163.02)

Applicants respectfully submit that FIGS. 9 and 10 and the corresponding description in paragraph [0077-0078] of the originally filed specification disclose generating an emulated surface EKG having a first emulated portion formed from only a portion of a first cardiac signal and a second emulated portion formed from only a portion of a second cardiac signal as recited in the claimed invention.

For example, originally filed paragraph [0077] discloses that FIG. 10 "illustrates exemplary RA channel signal 309 (also shown in FIG. 8) and specifically shows a first baseline point 410, found within a pre-R-wave window 411, and a second baseline point

412, found within a post-T-wave window 413. Once the baseline points have been identified within the RA channel signals for a given heart beat, corresponding points in time within the RV channel signals are identified, at step 414. Then portions of the RA channel signals occurring between the pair of baseline points are extracted, at step 416. Simultaneously, portions of the RV channel signals occurring outside of the baseline points are extracted, at step 418. At step 420, the extracted portions of the RA and RV signals for the given heart beat are combined using the baseline points as concatenation points." (Underlining added for emphasis only). An exemplary resulting concatenated signal, 422, for a single heart beat is shown in **FIG. 11** as described in paragraph [0078].

Applicants respectfully submit that the specification clearly discloses generating an emulated surface EKG from the concatenation of only a portion of a first signal that falls between concatenation points and only a portion of a second signal that lies outside the concatenation points. Thus, the originally filed specification makes clear that Applicants had in their possession a system and method for generating an emulated surface EKG signal having a first emulated portion formed from only a portion of a first cardiac signal and a second emulated portion formed from only a portion of a second cardiac signal as recited in the claimed invention.

The Examiner rejected claims 1-2 and 9-16 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 5,740,811 to Hedberg et al. Applicants respectfully traverse this rejection.

Applicants' claimed invention as recited in claims 1 and 16 is directed to a method and corresponding system for emulating a surface electrocardiogram (EKG) of a patient. For example independent claim 1 recites a method comprised in part by sensing separate cardiac signals ... and selectively concatenating portions of the separate cardiac signals to yield an emulated surface EKG having a first emulated portion formed from only a portion of a first cardiac signal and a second emulated portion formed from only a portion of a second cardiac signal. (Underlining added for emphasis only). Applicants respectfully submit that neither Kroll et al. nor Hedberg et al. do not disclose or suggest the recited claim elements.

Rather, Hedberg et al. process in vivo signals and then add them together (in their entirety) to form the synthesized signal. Hedberg et al. disclose that the reason for adding the signals from the electrodes is that they will simulate a signal obtained from a bigger electrode. (Hedberg et al. col. 6, lines 63-65). For example, in FIG. 13 transforming units, which process each of the electrode outputs, are coupled to a combining unit by multipliers which individually weigh each signal under the control of a microprocessor. The combining unit includes a summation stage which sums the outputs of the multipliers (in their entirety) to form the synthesized surface ECG. (Hedberg et al. col. 8, lines 15-50). Thus, Hedberg et al. process individual signals from separate electrodes and sum them together in their entirety to form an emulated surface ECG.

The Examiner suggests that col. 5, lines 30-37 and FIG. 4 of Hedberg disclose that a portion of an emulated signal is formed from only a portion of a second signal. Applicants disagree. FIG. 4 of Hedberg actually shows recordings of signals registered from various implanted electrode sets as well as externally measured surface ECG. Hedberg then discloses that it can be seen from FIG. 4 that characteristics from the different recorded IEGMs can be recognized in the surface ECG. Thus, the signal disclosed in FIG. 4 of Hedberg is an external ECG signal measured on the patient's skin and is not generated from internal cardiac signals. Moreover, Hedberg does not disclose that portions of this signal are generated from a single internal cardiac signal but that features or events seen in the internal signals (i.e. the QRS) look similar to the same feature in the externally measured ECG.

Accordingly, Applicants respectfully submit that claims 1 and 16 are novel and non-obvious over Kroll et al. and Hedberg et al. and are therefore allowable. Applicants further submit that claims 2 and 9-15 that depend from claim 1 are allowable as is claim 1 and for additional limitations recited therein.

In light of the above amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

54.08

Date

PC

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